

Effective Date: July 11, 2012

CRITERIA FOR PRIOR AUTHORIZATION

Kuvan® (sapropterin)

PROVIDER GROUP: Pharmacy

MANUAL GUIDELINES: The following drug(s) require prior authorization:

Kuvan® (sapropterin)

CRITERIA: (must meet all of the following)

- Diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU) in the past 2 years (ICD-9 270.1).
- Age \geq 4 years.
- Patient must be on a Phe-restricted diet.
- Dose should not exceed 20mg/kg/day.
- Blood Phe levels checked at baseline, after 1 week of therapy, and at least one other time in the first month of therapy.
- Patients should have Phe levels checked with any increases in Kuvan® dosing.
- Prescriber must document patient responsiveness to Kuvan® (decreased Phe) one month after starting therapy (or when dosing increases occur). Patients whose Phe levels do not decrease after 1 month of 20mg/kg/day are non-responders and will be denied.

RENEWAL CRITERIA:

- Documented responsiveness to Kuvan® (i.e. continued decreased in Phe blood levels).
- Patient must be on a Phe-restricted diet.

Initial prior authorization will be approved for 2 months. Renewals will be approved for 6 months.